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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,725	11/16/2000	Ying Luo	A-68289-1/RMS/DHR	6653

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FLEHR HOHBACH TEST
ALBBRITTON & HERBERT LLP
Four Embarcadero Center - Suite 3400
San Francisco, CA 94111-4187

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

16

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/715,725

Applicant(s)
Luo et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. The Election filed September 23, 2002 (Paper No. 12) and the Response to Office Action (Paper No. 15) in response to the Office Action mailed July 17, 2002 are acknowledged and have been entered. Claims 26-30 are pending in the application and claim 28 and all limitations drawn to recombinant proteins encoded by a nucleic acid set forth in SEQ ID Nos 1,3,5,9 or a recombinant protein comprising an amino acid sequence of SEQ ID NO:2, 4, 6, 10 recited in claims 26-27 and 29-30 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 26, 27 and 29-30 are currently under prosecution.

2. Applicant's election with traverse of Group IV, claims 26-27. 29-30 in Paper No 15 is acknowledged. The traversal is on the ground(s) that it has been determined that up to ten sequences constitute a reasonable number of sequences for examination purposes and therefore examination of all of the sequences does not impose a serious burden upon the examiner. The argument has been considered but has not been found persuasive because of the complex nature of sequence searches. Given the time required for the Office to search a single sequence, the search of more than one sequence is an undue burden upon the Examiner and the Office. Applicant further argues that SEQ ID NO:8 comprises amino acid sequences of the other recited isoforms and that a search of SEQ ID NOS 2, 4, 5 and 10 would not significantly raise the Examiner's burden above the search directed to SEQ ID NO:8 alone. This argument has been considered but has not been found persuasive as the cited sequences are not identical and given the differences in the sequences, each protein would be expected to have a different function and further, for the reasons

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set forth above, search of all of the sequences would be an undue burden for the Examiner and for the Office because different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claim Objections

3. Claims 26, 27 and 29-30 are objected to because they recite non-elected limitations. Applicant is required to delete the non-elected limitations in response to this Action.

Claim Rejections - 35 USC § 112

4. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO:8 and therefore the written description is not commensurate in scope with the claims drawn to amino acid sequences having at least 90% identity to SEQ ID NO:8. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated DNA molecules comprising a sequence having 90% identity to SEQ ID NO:8

The specification discloses SEQ ID NO:8. The claim, as written, however, encompass polypeptides which vary substantially in amino acid composition.

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The instant disclosure of a single species of amino acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. Although drawn to the DNA art, the findings of the Courts are relevant to the instant rejection. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides. The specification proposes to discover other members of the genus by using isolation assays. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of a specific amino acid sequence and the ability to screen, is insufficient

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to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 26 is rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. US Patent No. 6,066,474.

The claim is drawn to a recombinant ING2 protein encoded by a nucleic acid set forth in SEQ ID NO: 7.

It is noted that for examination purposes, that the claim is not drawn to a protein encoded by "the" sequence set forth as SEQ ID NO:7. Further, the specification does not define an ING2 protein in any limiting fashion. Thus, for examination purposes, a recombinant ING2 protein is a cell cycle protein which has similarity to proteins belonging to a family of tumor suppressors wherein the cell cycle proteins can be identified by substantial nucleic acid and/or amino acid sequence identity to the sequences provided herein (p.6).

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US Patent No. 6,066,474 teaches SEQ ID NO:s 2 and 3 which are nucleotide sequences which encode SEQ ID NO:1 or a variant thereof which both have 65.7% identity with SEQ ID NO:7, and encode a protein which would (because of the substantial identity with SEQ ID NO:7) to encode an ING2 protein as defined by the specification since SEQ ID Nos 2 and 3 encode a protein which is highly homologous with (that is which has similarity to) a tumor suppressing protein family and since it has a substantial nucleic acid identity to the sequences provided in the specification, it is a cell cycle protein (see attached sequence search us-009-442-013-7.mi, results 1 and 2 and page 13, paragraph 6). Although the reference does not specifically teach that the encoded protein is an ING2 protein, the claimed encoded protein appears to be the same as the prior art encoded protein, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

7. Claims 29-30 appear to be allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

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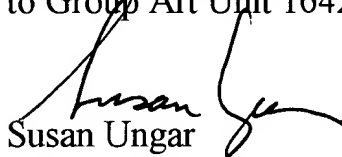
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(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
February 24, 2003